

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
CAMDEN DIVISION**

**IN RE: Valsartan N-Nitrosodimethylamine  
(NDMA), and Irbesartan Products Liability  
Litigation**

This Document Relates to All Actions

**MDL No. 2875  
Civil No. 19-02875 (RBK/JS)**

**SPECIAL MASTER ORDER NO. 54**

The discovery imbroglio addressed in this Order arose as a result of the ZHP Parties' production of an email dated July 27, 2017. The July, 27, 2017 email concerns potential nitrosamine contamination of Irbesartan, a blood pressure medication in the same family of sartans as Valsartan.

The circumstances surrounding production of this email caused Plaintiffs to suspect spoliation of evidence. For example, while the email bears a July 2017 date, the metadata accompanying its production suggested the email was created in June of 2018. And while the email listed a number of recipients, the email had not been within the document productions made on behalf of the recipients. The fact that the ZHP Parties have disclaimed knowledge of nitrosamine contamination of Valsartan prior to June of 2018, coinciding with the date-created metadata for the email, only served to buttress Plaintiffs' spoliation suspicions. As a result, Plaintiffs sought additional discovery related to the July, 2017 email.

By Special Master Order No. 20 (ECF No. 1233), the ZHP Parties were ordered to supplement their discovery in a number of respects, including to (a) produce the custodial files of the author of the July 27, 2017 email and other persons, (b) run new search terms suggested by the July, 2017 email across all custodians, and (c) produce documents concerning Valsartan

impurity testing. Dissatisfied with the supplemental discovery produced by the ZHP Parties, Plaintiffs have now moved to compel further production. (ECF No. 1405.) The ZHP Parties have submitted a comprehensive brief in opposition to the motion, along with 19 exhibits. (ECF No. 1485.) A hearing on the motion via Zoom was conducted on September 10, 2021. For the reasons that follow, Plaintiffs' motion will be granted in part.

## **DISCUSSION**

Plaintiffs contend that ZHP's supplemental production is deficient in the following seven respects: (1) the number of documents from various custodians is low; (2) ZHP has not produced the custodial file of the Chief of Staff of ZHP's President; (3) the production related to the July 27, 2017 email fails to include expected documents; (4) ZHP has not demonstrated compliance with the court-sanctioned ESI protocol (ECF No. 127) in relation to production of data from smartphones; (5) ZHP did not produce documents relating to certain meetings that took place once the nitrosamine contamination was disclosed at the insistence of Novartis in June of 2018; (6) the production of testing records is inadequate; and (7) ZHP has not produced documents relating to a meeting concerning a purported decision to not investigate certain testing anomalies. Each of these contentions will be addressed in turn. Before doing so, however, Plaintiffs' request for production of litigation hold notices and document retention policies will be discussed.

### **A. Litigation Hold Notices and Document Retention Policies**

Asserting that ZHP has demonstrated an unwillingness or inability to comply with its discovery obligations, Plaintiffs have requested access to ZHP's litigation hold notices and

document retention policies. During the September 10th hearing, ZHP was directed to submit its litigation hold notices for *in camera* review.

ZHP timely complied, submitting hold notices from Jun Du dated September 12, 2018, March 5, 2019, and November 19, 2019. The first Notice is for Valsartan, the second is for Irbesartan and Losartan, and the third is for Valsartan, Irbesartan, and Losartan. The Notices, which are nearly identical, appear to be comprehensive and sufficient on their face. In the absence of evidence that relevant documents have been destroyed or lost, production of the litigation hold notices to Plaintiffs will not be compelled at this time. *See Nekich v. Wisconsin C. Ltd.*, CV 16-2399 (JNE/DTS), 2017 WL 11454634, at \*5 (D. Minn. Sept. 12, 2017); *Tracy v. NVR, Inc.*, 04-CV-6541L, 2012 WL 1067889, at \*9 (W.D.N.Y. Mar. 26, 2012).

There is, however, one matter that ZHP will be required to address. Exhibit 29 to Plaintiffs' Motion to Compel indicates that there were 11 hold notices sent on behalf of Jun Du. Although the dates of the three notices provided for *in camera* review approximate the dates listed on Exhibit 29, they are not exact matches. ZHP will be directed to provide an affidavit stating whether the Notices provided for *in camera* review were the only Notices issued and whether the Notices sent in December of 2019 were identical to the Notice dated November 19, 2019 that the ZHP Parties provided for *in camera* review.

As to document retention policies, counsel for ZHP represented during the September 10th hearing that they would be produced. ZHP will be required to provide an affidavit stating whether all document retention policies have in fact been produced.

#### **B. Alleged deficiencies in custodial productions**

Pointing to the relatively low number of documents produced and the absence of emails before certain dates, Plaintiffs assert that "ZHP has failed to preserve and/or produce documents

crucial to this litigation.” (Brief in Support of Motion to Compel ZHP’s Supplemental Production at 8.) For example, Plaintiffs state that the author of the July, 27, 2017 email had less than 570 documents produced, with the earliest being dated January 13, 2018, more than 5 years after he began working at ZHP and nearly six months after his July 27, 2017 email. As to Baohua Chen, President of ZHP, Plaintiffs assert that ZHP’s production of only 326 documents in his custodial file, all of which post-date January 24, 2018, strains credulity.

ZHP notes in response that the document production count is much higher after application of a metadata overlay. It also states that the relatively low document count is to be expected in that this production is occurring well after production by the 80 initially-identified document custodians and the peripheral role played by most of the newly added document custodians. ZHP has also provided a credible explanation for the date-created anomaly on the July 27, 2017 email. The email itself was located in data recovered from a damaged hard drive. The source path for the email is “/F/Old Desktop/Projects Irbesartan,” and the created date of June 2018 is consistent with the testimony that files were transferred from a damaged computer to a new computer in June of 2018. Furthermore, unlike *Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631 (D.N.J. Aug. 4, 2009), on which Plaintiffs rely, there is no testimony here that there was a failure to follow litigation hold advice. Nor is there evidence of the loss of any particular data. Notably, Plaintiffs do not seek spoliation sanctions; they seek instead an order compelling the ZHP Parties to re-do their searches for discoverable documents. Given the extensive discovery that has occurred to date and the lack of direct evidence of document destruction or loss, the ZHP Parties will not be required to conduct another search for relevant evidence.

**C. The custodial file for Xiaofang (“Maggie”) Kong**

Ms. Kong is the Chief of Staff to ZHP's President, Baohua Chen. In that capacity, she was responsible for arranging meetings involving Mr. Chen in reaction to the discovery of nitrosamine contamination of Valsartan. Furthermore, as Mr. Chen did not use email, communications within ZHP directed to Mr. Chen were routed through Ms. Kong.

Because she served as the conduit for communications between Mr. Chen and others, ZHP asserts that many of the communications routed through Ms. Kong will be covered by the attorney-client privilege, and has objected to production of her custodial file on proportionality grounds. The problem with this objection is that there has been no review of Ms. Kong's custodial file. A document count alone cannot suffice to show undue burden as part of a proportionality analysis.

During the September 10, 2021 hearing counsel for ZHP also raised the potential problem that China's recently adopted privacy law may foreclose production Ms. Kong's custodial file. That fact, however, cannot preclude ordering production of the file.

During the hearing, I stated that production of the contents of Ms. Kong's custodial file, subject to claims of privilege, will be ordered, with ZHP raising "whatever issues you have in terms of there being some supervening, superseded change [in law] that precludes production." (Sept. 10, 2021 Tr. (ECF No. 1573) at 63.) Accordingly, ZHP will be ordered to produce the relevant, non-privileged parts of Ms. Kong's custodial file, and the impact of China's recently-adopted privacy law will be addressed if raised as a ground for withholding from discovery this potentially significant source of discovery.

#### **D. Production related to the July 27, 2017 email**

There was an investigation that preceded the issuance of the July 17, 2017 email. That investigation was assigned the designation, "TC-201729," and a copy of the resulting draft report

is presented by Plaintiffs as Ex. 14 to their Motion to Compel. It has bates numbering beginning at ZHP02710347. Plaintiffs complain that this document was produced in PDF format only without any metadata, even though it was undoubtedly created via computer. Plaintiffs also complain that, while ZHP was ordered to produce any responsive, non-privileged documents related to this investigation, only two documents (Ex. 15 and Ex. 16 to ZHP's motion) were produced.

During the September 10th hearing counsel for ZHP did not have an explanation as to why Exhibit 14 was produced in PDF without metadata. Nor was counsel able to explain why only two handwritten documents (Ex. 15 and Ex. 16) were produced in response to the search term, "TC-201729." Accordingly, ZHP will be ordered to produce ZHP02710347, et seq., in its native format with metadata, and ZHP will be directed to search again for documents bearing the designation, "TC-201729."

#### **E. Smartphone data**

Plaintiffs next complain that ZHP failed to comply with the Court-sanctioned ESI Protocol, ECF No. 127. Plaintiffs contend that the protocol required production of all data from smartphone applications, and no such data have been produced. Plaintiffs further observe that deposition discovery revealed that ZHP failed to collect smartphones from key custodians to examine them for responsive information. As ZHP correctly notes, however, the protocol did not require production of handheld device data, but simply identified data from smartphone applications as an example of ESI. (ECF No. 127 at 2.) The protocol specifically states that mere inclusion of a data source in the protocol did not constitute a representation that "such ESI exists within the parties' data sources *or that it will be produced.*" (*Id.*; emphasis added.) Under

these circumstances, ZHP will not be compelled to retrieve handheld devices from key custodians and search the devices for responsive information.

**F. Documents relating to meetings that took place once the nitrosamine contamination was disclosed**

Plaintiffs initially challenged ZHP's failure to produce emails, meeting minutes, and calendar invitations concerning meetings Min Li attended with Baohua Chen following the disclosure of nitrosamine contamination, as well as their failure to produce documents relating to Min Li's meetings with "multi-national companies" in relation to a decision to limit investigation of "unknown peaks smaller than 20." During the September 10th hearing, however, Plaintiffs stated that they would "accept what the production is at this time." (Sept. 10, 2021 Tr. at 78, 79.) Accordingly, no additional action on those matters will be taken at this time.

**G. Nitrosamine testing production**

Special Master Order No. 20 (ECF No. 1233) required ZHP to "produce any additional responsive and non-privileged documents related to the March 12, 2018 testing investigation of valsartan API Batch No. C55-18-053M ... as well as any additional responsive and non-privileged documents relating to the batch testing referenced in PRINSTON0075797." There appears to be no dispute that the testing results have not been produced. ZHP contends that production of the test results for more than 7,000 batches of Valsartan would be extremely labor-intensive and cost millions of dollars. It also contends that the testing concerned Valsartan destined for countries other than the United States, and thus has little relevance here. Plaintiffs respond that the destination of the product is not determinative; what is dispositive is whether the facility where the product was produced also made Valsartan that was to be sent to the United States.

The Macro Discovery Order entered by Magistrate Judge Schneider in this case on November 25, 2019 (ECF No. 303) provided that “Plaintiffs are entitled to discovery regarding *any* test that could identify the presence of nitrosamine contamination. Also, testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the Valsartan API and Valsartan is relevant.” (Emphasis added.) The test results sought by Plaintiffs appear to fall within the requirements of that order. But that order did not address the proportionality concerns now being raised by ZHP, which claims that production would require scanning thousands of over-sized records and manually entering metadata. The cost, ZHP asserts, would run into millions of dollars. ZHP, however, has not presented competent evidence to substantiate this assertion.

Otherwise permissible discovery must be limited if “the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.” *Carr v. State Farm Mut. Automobile Ins. Co.*, 312 F.R.D. 459, 468 (N.D. Tex. 2015). The burden of showing the cost of compliance with discovery obligations, however, “cannot be sustained with bald generalizations or a conclusory assertion that production will be time-consuming and/or expensive.” *Waskul v. Washtenaw County Community Mental Health*, CV 16-10936, 2021 WL 5049154, at \*5 (E.D. Mich. Oct. 31, 2021) (internal quotation marks and citation omitted). The objecting party must “submit affidavits or other evidence to substantiate its objections.” *Cratty v. City of Wyandotte*, 296 F. Supp. 3d 854, 859 (E.D. Mich. 2017).

Perhaps due to the context in which this issue arose, with Plaintiffs presenting a motion to compel supplemental production, ZHP did not submit affidavits or other evidence of the burden

of producing testing results. It also did not present options by which the testing results may be obtained by Plaintiffs while minimizing the cost to ZHP. For instance, if the records exist in hard copy, can Plaintiffs be allowed to inspect the records and determine what needs to be scanned or otherwise produced? And if metadata exist, can the metadata be produced without manual entry? Is there some other way in which the testing results can be shared? It is reasonable to infer from ZHP's statements that the testing records exist and there must be a way for Plaintiffs to have access to the results without imposing an undue burden and expense.

ZHP will be given an opportunity to address these matters and present an appropriate evidentiary record before a final decision on production of the testing records is made, and Plaintiffs will be given an opportunity to respond. The parties will be directed to meet and confer on production of testing records and explore alternatives that give Plaintiffs the requested access while minimizing the expense and burden to ZHP.

**NOW, THEREFORE, this 12th DAY OF NOVEMBER, 2021,** for the reasons set forth above, **IT IS HEREBY ORDERED THAT:**

1. No later than November 22, 2021, the ZHP Parties shall file an affidavit indicating (a) whether the litigation hold notices submitted for *in camera* review were the only notices issued in this matter; (b) whether the notices sent in December of 2019 are identical to the Notice dated November 19, 2019 and submitted for *in camera* review; and (c) whether all document retention policies have been produced.
2. No later than November 22, 2021, the ZHP Parties shall produce the relevant, non-privileged parts of Xiaofang Kong's custodial file.

3. No later than November 22, 2021, the ZHP Parties shall produce the document bearing bates number ZHP02710347, et seq., in its native format with metadata, and produce all non-privileged documents bearing the designation, “TC-201729.”
4. Plaintiffs’ request for production of smartphone data is denied.
5. Counsel for Plaintiffs and the ZHP parties shall meet and confer on the production of testing records and report in writing not later than November 30, 2021 on their efforts to resolve this dispute. If the parties are unable to resolve this dispute, the ZHP Parties shall present, no later than December 7, 2021, competent evidence of the anticipated cost of producing the testing records sought by Plaintiffs, along with an affidavit addressing other, less costly options for production of the testing results.
6. In all other respects, Plaintiffs’ Motion to Compel ZHP’s Supplemental Production (ECF No. 1405) is denied.

s/ Thomas I. Vanaskie  
Hon. Thomas I. Vanaskie (Ret.)  
Special Master